

he reconsider his rejection criteria based on the following analysis.

In his third item, the Examiner states that Osborne “teaches a supraglottic and perilaryngeal apparatus for insertion of a supraglottic airway by a medical practitioner into a patient’s upper airway.” An important feature of Applicant’s apparatus is that it lifts the epiglottis upward so that the apparatus may be situated in the vallecula. On the contrary, Osborne in page 1, line 60 states that his tongue-depressing insufflator “forces the tongue downward to expose the pharynx behind the soft palate.” It should be obvious to those skilled in the art that Osborne is structured and functions wholly differently from the instant invention. Firstly, the instant invention does not push the tongue downwardly, but compresses and retracts the tongue. Secondly, the area behind the soft palate is rostral to the area that the instant invention focuses upon. Indeed, it should be evident that inherently in emplacing supraglottic airways, the area behind the soft palate should be avoided. Thirdly, Osborne makes no mention of nor reference to the vallecula. Hence, it should be evident that Osborne is inapposite the instant invention because it is designed to be used for an area considerably rostral to the laryngeal outlet: the functions of spraying medication and simultaneously illuminating the tonsils is significantly different and anatomically remote from the instant design and purposes of Applicant’s apparatus.

In line 64, Osborne further states that his insufflator may be to “draw the tongue forward without compression.” Applicant, as an experienced anesthesiologist, fails to comprehend how the Osborne device accomplishes its announced purpose of drawing the tongue forward in the absence of compression. Applicant notes, however, that

practitioners in the art occasionally accomplish this purpose with fiberoptic intubation by using a gauze to grab the tongue and then pull it forwardly out of the mouth of a sedated patient whose tongue has been numbed. Thus, the tongue has been pulled forwardly without compression. It is evident to Applicant that the Osborne device cannot function without some measure of compression of the tongue.

The depressor portion of Osborne's device is oval (see, e.g., line 96) in contrast to the instant retractor apparatus which has a longer and curved mid-section. The shield portion of Applicant's apparatus is flat not curved as in Osborne's device. It should be appreciated that the proximal portion of the instant supraglottic retractor device is rather narrow to accommodate an area that is neither broad nor wide. Indeed, the actual area of tongue compression in the buccal cavity is considerably smaller than it is flat. This is, of course, in stark contrast with the shield area proximal to the tip of the instant retractor device wherein the actual area in contact with the tongue increases. While, as the Examiner states, Osborne teaches an apparatus with the handle member, the arcuate offset member, and the compressor-lever shield member being integrally constructed — with the compression-lever shield member being comprising a substantially flat and concave configuration — the instant retractor apparatus has a longer mid-section and a flat tip. On the other hand, the Osborne apparatus is curved relative to its shaft or distant segment. It should also be considered by the Examiner that Osborne's description is obviously contradictory and consequently confusing: in line 104, Osborne states that, in the course of using his device, the tongue is "depressed and drawn forward."

In item 10, the Examiner points out that, regarding Claims 3-7, Osborne teaches essentially all of the limitations except for how the handle member and arcuate offset member are interconnected and how the arcuate offset member and the compression-lever shield member are connected and what specifically are the means of connection. The Examiner then concludes that it would be obvious to one of ordinary skill in the art to modify the apparatus of Osborne so that the various components of the apparatus are interconnected to each other. While this conclusion may be facially correct, Applicant respectfully points out that a practitioner sufficiently skilled in the art would recognize that the handle member could be of one size while the other component members would be variable to accommodate particular patient anatomical attributes. More particularly, a plurality of factors affect the optimal selection of size of the various components of Applicant's apparatus, including buccal cavity size, tongue size, length of neck, a classification applied by anesthesiologists called "Mallampati," and the thyromental distance. Accordingly, as should be appreciated by those skilled in the art, it is not a simple situation of merely interconnecting and disconnecting components in the instant apparatus, but a practitioner must carefully engage in airway assessment as a prerequisite to proper selection of each of the components so that the assembled apparatus is compatible with and optimal for application to the patient's airway.

The Examiner also states (item 11), citing Gomez (US Patent No. 6,053,166), that it is known in the art to provide a marker means disposed at an end proximal to the handle member for guiding the medical practitioner. Applicant respectfully points out

that Gomez relates to an intubating device designed to direct the endotracheal tube anteriorly through the vocal cords. It should be apparent to those skilled in the art that this guiding function pertains to directing a tube passing through the assembly into the trachea. Contrariwise, the instant retractor device is designed to function above or circumferentially of the laryngeal inlet. Accordingly, the markers on the instant assembly are designed to gauge the distance of the tip of the guide from the lips. It should be evident that this design-purpose is to prevent the tip from being inserted too far so that it will not curve forward and face the vallecula; if this occurs, the endotracheal tube will then impact the vallecula and will not enter the trachea. A significant difference, of course, is that Gomez's apparatus, unlike the instant apparatus, attempts to stay away from the vallecula and concomitantly approach the laryngeal inlet from its undersurface. It will be appreciated that prerequisite for properly placing a tube into a patient's laryngeal inlet — through the vocal cords and into the trachea — distance becomes very important. For most patients, endotracheal tube position is optimal when the tube marker is 20-24 cm at the patients' lips, i.e., the distance to the tip of the tube is 20-24 cm. It will be understood by those skilled in the art, however, that this range is considerable and is influenced by patient chin movements. Consequently, bringing a patient into the equation, in actuality, is inappropriate since a panoply of anatomical considerations are in-play.

To overcome the Examiner's rejection, Applicant has amended independent Claim 1 to limit the structure of the compressor-lever shield member to being flat. Applicant has

also corrected the spelling of the "vallecula" in Claims 1 and 10. Attached hereto for the Examiner's convenience are clean copies of Claims 1 and 10.

In view of the foregoing, Applicant respectfully submits that amended Claims 1 and 10, and original Claims 2-9, and 11 are in condition for allowance. Allowance of Claims 1-11 is hereby solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Al Harrison', is written over a horizontal line.

Al Harrison
Registration No. 31,708
Harrison & Egbert
1018 Preston, Suite 100
Houston, Texas 77002
Tel (713) 223-4034
FAX (713) 224-7950
E-Mail VirtuAl@allegal.com

CLEAN COPY OF AMENDED CLAIMS 1 AND 10

1. In a patient's mouth including a buccal cavity, a pharyngeal cavity, an epiglottis, a vallecula, and a tongue, a superglottic and peri-laryngeal apparatus for insertion of a supraglottic airway by a medical practitioner into said patient's upper airway, said apparatus comprising:

a handle member;

an arcuate offset member disposed medially of said handle member and a flat compressor-lever shield member;

said compressor-lever shield member configured to continuously widen from said arcuate offset member to a substantially broad tip means disposed at said shield member's leading, distal edge, and adapted to match size and configuration of the anatomical features of said patient's upper airway; and

said arcuate offset member configured to enable said shield member to reach said supraglottic region proximal to the base of said tongue and said vallecula so as to provide sufficient leverage to enable said medical practitioner to compress and lift said tongue and to simultaneously lift said epiglottis in said pharyngeal cavity, while simultaneously flattening said tongue in said buccal cavity, for creating sufficient space in both said buccal cavity and said pharyngeal cavity to enable said medical practitioner to rapidly insert said supraglottic airway while minimizing tissue trauma and post-procedural patient discomfort.

10. The apparatus recited in Claim 1, wherein said compression-lever shield member comprises a perimeter buffered edge to prevent tissue trauma as said

1 shield member is advanced by said medical practitioner through said patient's
2 pharyngeal cavity into said vallecula.

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